Comparison of reporting of ethnicity in US and European randomised controlled trials

Commentary: Methodological reasons for not gaining prior informed consent are sometimes justified

Angus J Dawson

Informed consent is generally required before medical research interventions.[1–3] Despite this, good reasons not to seek such consent often exist. Examples might include research with incompetent patients, research using anonymised tissue samples, and certain types of epidemiological research.[4] Another reason, often forgotten, is where there are methodological reasons not to seek consent in advance of the intervention. Boter et al's study represents such an occasion.[1] Informed consent could not be given before the research as the methodology involved the patients assessing their own quality of life. Requiring prior consent would have led to potentially biased results.[5]

Is this study unethical because informed consent was not gained in advance? Leaving aside the fact that the research could not have been accomplished if such consent were required, such a claim raises an important ethical issue. Arguably, no ethical principle should be absolute in this way. Situations are complex, and minor changes can make a significant difference to the way that we assess them. Different ethical and methodological issues need to be weighed against each other and a defensible judgment made on the basis of all of the relevant factors.

In this case, the procedure for consenting was ethically justified because the study considers an important issue; the results could be achieved with blinding to the issue to be investigated; and any possible harm to the participants was negligible.

Even if we agree that the alternative of not doing the study would have treated the patients with more respect,[6] it is not clear it would have been more ethical, as the results of the study will improve the quality of life of stroke victims.[5] Blindly applying absolute principles such as "always gain prior informed consent" does not guarantee ethical outcomes. Such an approach might well be harmful, as potentially beneficial studies will not be done.

One concern about the study's approach might be that it still places too much emphasis upon consent.[7] Informing the participants in advance that some information about the research was withheld could have caused anxiety. As a result, participants might have imagined themselves in all sorts of distressing scenarios. An alternative would have been to say nothing about the consent issue until after the study was completed. It is not clear that the "modified" informed consent procedure is preferable. However, it is important that this research found that most participants could, retrospectively, appreciate the methodological reasons for not seeking prior consent, and they generally seemed happy to be involved in such research.

Researchers, journals, and the members of research ethics committees should all take note of these findings and should be more willing to weigh up the appropriateness of seeking prior informed consent given the methodology employed in a study. An absolute requirement to gain always an informed consent may do more harm than good.

Competing interests: None declared.

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Comparison of reporting of ethnicity in US and European randomised controlled trials

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Increasing evidence shows that different ethnic groups respond differently to educational, psychosocial, and pharmacological interventions. If diverse communities are to benefit from the implementation of appropriately derived evidence then it is imperative that the ethnic diversity of populations under study are reflected in clinical trials. In the United States, since 1993, the National Institutes of Health have instituted policy insisting that minority groups are represented in study samples unless there is a compelling reason not to do so.[1] However, no comparable legislation exists in Europe. We sought to compare reporting of ethnicity in published reports of US and European randomised controlled studies.

Methods and results

We searched Medline for reports of trials published in 2002 using the Cochrane optimal search strategy.[2] We

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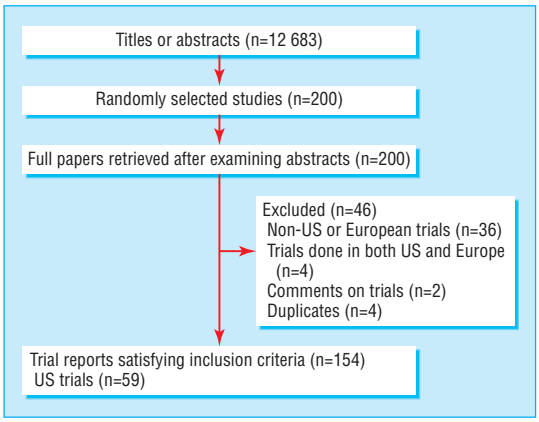

Selection of trial reports

downloaded titles and abstracts of study reports into the reference manager database and randomly selected 200 reports for further scrutiny. We identified trials done in the United States and Europe and got full text reports. We assessed any description of the ethnicity of participants in detail. We used a broad definition of ethnicity that included any reference to race, ethnic origin, language, or nationality. We categorised studies as either detailing the ethnicity of subjects or not. Two reviewers independently extracted data on to a prepiloted sheet; they resolved disagreements through discussion.

We used descriptive statistics to find the proportion of studies reporting information on the ethnicity of subjects and used the χ^2 test to compare reporting of ethnicity in United States and European published reports.

For 80% power at the 5% significance level (two tailed test) of detecting a difference from 20% to 40% in the proportion of studies reporting on ethnicity, assuming that one in five European trials detailed this information, we needed to identify a total of 182 trials.

Our searches retrieved 12 683 titles and abstracts, from which we selected 200 for further scrutiny. Of these, 154 studies satisfied our inclusion criteria (figure). A total of 59 (38%) of these trials were based in the United States and 95 (62%) in Europe. Overall, 30 (19%) reports included information on the ethnic profile of participants. American studies were significantly more likely to report on ethnicity than European studies (23 *v* 7; 39% *v* 7%; relative risk 5.3, 95% confidence interval 2.4 to 11.6; $P < 0.0001$).

Comment

American studies are five times more likely than European trials to report information on the ethnicity of participants. The random selection procedures adopted and the standardised and independent extraction of data with an initially agreed approach to handle disagreements should have minimised the risk of selection bias or information bias accounting for these findings.

Our results seem likely to reflect active policies in the United States. For example, all federally supported programmes with sufficient sample size are required to report statistics according to race or ethnicity.[3] None the less, it is still concerning that only two fifths of recently published trials from the United States report on the ethnicity of participants. Possible explanations include known difficulties in identifying, enrolling, and following up minority ethnic populations in trials. Another possible factor is the argument that ethnicity reporting is only important in specific disease areas with known ethnic disparities. Relevant here are recent data showing that in the study of such conditions 59% of US trials report on the ethnicity of participants.[4]

Mechanisms to facilitate inclusion and standards to ensure reporting of minority ethnic communities in studies are needed. These reporting standards are absent in current CONSORT requirements and we suggest that the merits of insisting on presentation of such data, where appropriate, should be debated.[5] In particular, European governments should consider the US model for promoting inclusion of ethnic minority participants in research.

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Endpiece

Misunderstood

Said the little boy, "Sometimes I drop my spoon."
Said the old man, "I do that too."
The little boy whispered, "I wet my pants."
"I do that too," laughed the old man.
Said the little boy, "I often cry."
The old man nodded, "So do I."
"But worst of all," said the little boy, "it seems grown-ups don't pay attention to me." And he felt the warmth of a wrinkled old hand.
"I know what you mean," said the little old man.

Silverstein S. The little boy and the old man. In: *A light in the attic.* New York: Harper Collins, 1981

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